

Exhibit 3



US011648090B2

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Li et al.

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(54) **MULTILAYER POLYMER SHEETS**

(71) Applicant: **ALIGN TECHNOLOGY, INC.**, San Jose, CA (US)

(72) Inventors: **Chunhua Li**, Cupertino, CA (US); **Yan Chen**, Cupertino, CA (US); **Heinz Pudleiner**, Krefeld (DE); **Klaus Meyer**, Dormagen (DE); **Joerg Nickel**, Dormagen (DE); **Craig Pehlert**, Lenox, MA (US)

(73) Assignee: **Align Technology, Inc.**, San Jose, CA (US)

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(Continued)

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CPC **A61C 7/08** (2013.01); **B29C 51/14** (2013.01); **B32B 7/022** (2019.01); **B32B 25/08** (2013.01); **B32B 25/20** (2013.01); **B32B 27/08**

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(Continued)

(58) **Field of Classification Search**

None

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,253,828 A * 3/1981 Coles A61C 7/00
433/6
4,410,595 A * 10/1983 Matsumoto B32B 27/34
428/424.4

(Continued)

FOREIGN PATENT DOCUMENTS

CN 103374211 A * 10/2013
CN 108394152 A * 8/2018

(Continued)

OTHER PUBLICATIONS

"Overview of Materials for PETG Copolyester" (<http://www.matweb.com/search/DataSheet.aspx?MatGUID=4de1c85bb946406a86c52b688e3810d0&ckck=1>) (webpage retrieved on Oct. 27, 2020) (Year: 2020).*

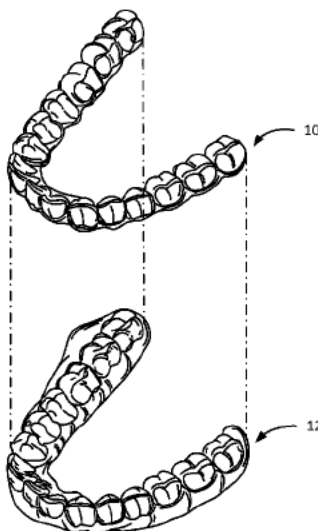
Primary Examiner — Vivian Chen

(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) **ABSTRACT**

Multilayer polymer sheets are provided, as well as related methods, systems, and appliances.

11 Claims, 8 Drawing Sheets



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Related U.S. Application Data		5,335,675	A *	8/1994	Wheeler	B29C 49/00
No. 16/835,101, filed on Mar. 30, 2020, now Pat. No. 11,213,369, which is a continuation of application No. 15/476,655, filed on Mar. 31, 2017, now Pat. No. 10,973,613, which is a division of application No. 13/470,681, filed on May 14, 2012, now Pat. No. 9,655,691.						128/842
		5,820,368	A	10/1998	Wolk	
		6,386,864	B1	5/2002	Kuo	
		6,450,807	B1	9/2002	Chishti et al.	
		6,471,511	B1	10/2002	Chishti et al.	
		6,607,382	B1	8/2003	Kuo et al.	
		6,746,757	B1 *	6/2004	Takagi	B32B 27/34
						428/476.3
		6,783,604	B2	8/2004	Tricca	
		6,790,035	B2	9/2004	Tricca et al.	
		6,814,574	B2	11/2004	Abolfathi et al.	
		6,830,450	B2	12/2004	Knopp et al.	
		6,947,038	B1	9/2005	Anh et al.	
		7,074,039	B2	7/2006	Kopelman et al.	
		7,104,792	B2	9/2006	Taub et al.	
		7,160,107	B2	1/2007	Kopelman et al.	
		7,192,273	B2	3/2007	McSurdy, Jr.	
		7,201,575	B2 *	4/2007	Adell	A61C 13/0001
						433/80
		7,347,688	B2	3/2008	Kopelman et al.	
		7,448,514	B2	11/2008	Wen	
		7,481,121	B1	1/2009	Cao	
		7,543,511	B2	6/2009	Kimura et al.	
		7,553,157	B2	6/2009	Abolfathi et al.	
		7,600,999	B2	10/2009	Knopp	
		7,641,828	B2 *	1/2010	DeSimone	A61C 7/08
						264/16
		7,658,610	B2	2/2010	Knopp	
		7,766,658	B2	8/2010	Tricca et al.	
		7,771,195	B2	8/2010	Knopp et al.	
		7,854,609	B2	12/2010	Chen et al.	
		7,871,269	B2	1/2011	Wu et al.	
		7,878,801	B2	2/2011	Abolfathi et al.	
		7,878,805	B2	2/2011	Moss et al.	
		7,914,283	B2	3/2011	Kuo	
		7,947,508	B2	5/2011	Tricca et al.	
		8,152,518	B2	4/2012	Kuo	
		8,172,569	B2	5/2012	Matty et al.	
		8,235,715	B2	8/2012	Kuo	
		8,292,617	B2	10/2012	Brandt et al.	
		8,337,199	B2	12/2012	Wen	
		8,401,686	B2	3/2013	Moss et al.	
		8,517,726	B2	8/2013	Kakavand et al.	
		8,562,337	B2	10/2013	Kuo et al.	
		8,641,414	B2	2/2014	Borovinskih et al.	
		8,684,729	B2	4/2014	Wen	
		8,708,697	B2	4/2014	Li et al.	
		8,771,149	B2	7/2014	Rahman et al.	
		8,899,976	B2	12/2014	Chen et al.	
		8,899,977	B2	12/2014	Cao et al.	
		8,936,463	B2	1/2015	Mason et al.	
		8,936,464	B2	1/2015	Kopelman	
		9,022,781	B2	5/2015	Kuo et al.	
		9,108,338	B2	8/2015	Sirovskiy et al.	
		9,119,691	B2	9/2015	Namiranian et al.	
		9,161,823	B2	10/2015	Morton et al.	
		9,241,774	B2	1/2016	Li et al.	
		9,326,831	B2	5/2016	Cheang	
		9,433,476	B2	9/2016	Khardekar et al.	
		9,610,141	B2	4/2017	Kopelman et al.	
		9,655,691	B2 *	5/2017	Li	B32B 7/022
		9,655,693	B2 *	5/2017	Li	B32B 27/40
		9,675,427	B2	6/2017	Kopelman	
		9,700,385	B2	7/2017	Webber	
		9,744,001	B2	8/2017	Choi et al.	
		9,844,424	B2	12/2017	Wu et al.	
		10,045,835	B2	8/2018	Boronkay et al.	
		10,052,176	B2 *	8/2018	Li	A61C 7/08
		10,111,730	B2	10/2018	Webber et al.	
		10,150,244	B2	12/2018	Sato et al.	
		10,201,409	B2	2/2019	Mason et al.	
		10,213,277	B2	2/2019	Webber et al.	
		10,299,894	B2	5/2019	Tanugula et al.	
		10,363,116	B2	7/2019	Boronkay	
		10,383,705	B2	8/2019	Shanjani et al.	
		D865,180	S	10/2019	Bauer et al.	
		10,449,016	B2	10/2019	Kimura et al.	
		10,463,452	B2	11/2019	Matov et al.	
(51)	Int. Cl.					
	<i>B32B 7/022</i>	(2019.01)				
	<i>B32B 25/08</i>	(2006.01)				
	<i>B32B 25/20</i>	(2006.01)				
	<i>B32B 27/08</i>	(2006.01)				
	<i>B32B 27/30</i>	(2006.01)				
	<i>B32B 27/32</i>	(2006.01)				
	<i>B32B 27/34</i>	(2006.01)				
	<i>B32B 27/36</i>	(2006.01)				
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	<i>B29C 51/14</i>	(2006.01)				
	<i>B32B 25/14</i>	(2006.01)				
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	<i>A61F 5/56</i>	(2006.01)				
	<i>A61C 19/06</i>	(2006.01)				
	<i>A61C 7/00</i>	(2006.01)				
	<i>A63B 71/08</i>	(2006.01)				
	<i>B29K 67/00</i>	(2006.01)				
	<i>B29K 75/00</i>	(2006.01)				
	<i>B29L 31/00</i>	(2006.01)				
(52)	U.S. Cl.					
	CPC	<i>A61C 7/00</i> (2013.01); <i>A61C 13/00</i> (2013.01); <i>A61C 19/06</i> (2013.01); <i>A61F 5/56</i> (2013.01); <i>A63B 71/085</i> (2013.01); <i>B29K 2067/00</i> (2013.01); <i>B29K 2075/00</i> (2013.01); <i>B29K 2995/007</i> (2013.01); <i>B29K 2995/0026</i> (2013.01); <i>B29K 2995/0077</i> (2013.01); <i>B29K 2995/0082</i> (2013.01); <i>B29L 2031/753</i> (2013.01); <i>B32B 25/14</i> (2013.01); <i>B32B 27/283</i> (2013.01); <i>B32B 27/30</i> (2013.01); <i>B32B 27/302</i> (2013.01); <i>B32B 2250/03</i> (2013.01); <i>B32B 2250/24</i> (2013.01); <i>B32B 2250/40</i> (2013.01); <i>B32B 2274/00</i> (2013.01); <i>B32B 2307/40</i> (2013.01); <i>B32B 2307/412</i> (2013.01); <i>B32B 2307/50</i> (2013.01); <i>B32B 2307/51</i> (2013.01); <i>B32B 2307/536</i> (2013.01); <i>B32B 2307/54</i> (2013.01); <i>B32B 2307/546</i> (2013.01); <i>B32B 2319/00</i> (2013.01); <i>B32B 2323/00</i> (2013.01); <i>B32B 2323/04</i> (2013.01); <i>B32B 2323/10</i> (2013.01); <i>B32B 2323/16</i> (2013.01); <i>B32B 2333/04</i> (2013.01); <i>B32B 2367/00</i> (2013.01); <i>B32B 2371/00</i> (2013.01); <i>B32B 2375/00</i> (2013.01); <i>B32B 2377/00</i> (2013.01); <i>B32B 2383/00</i> (2013.01); <i>B32B 2535/00</i> (2013.01); <i>B32B 2555/00</i> (2013.01); <i>Y10T 428/31551</i> (2015.04); <i>Y10T 428/31565</i> (2015.04); <i>Y10T 428/31786</i> (2015.04)				
(56)	References Cited					
	U.S. PATENT DOCUMENTS					
	4,739,012	A *	4/1988	Hagman	C08L 27/06	
					525/166	
	4,755,139	A *	7/1988	Abbate	A61C 7/08	
					433/6	
	4,843,124	A *	6/1989	Wolfe, Jr.	C08L 11/00	
					525/173	

US 11,648,090 B2

Page 3

(56)	References Cited			2008/0248438	A1 *	10/2008	DeSimone	A61C 7/08
	U.S. PATENT DOCUMENTS							433/6
	10,470,847	B2	11/2019	Shanjani et al.				
	10,517,701	B2	12/2019	Boronkay	2008/0286716	A1	11/2008	Sherwood
	10,537,406	B2	1/2020	Wu et al.	2008/0286717	A1	11/2008	Sherwood
	10,537,463	B2	1/2020	Kopelman	2009/0280450	A1	11/2009	Kuo
	10,548,700	B2	2/2020	Fernie	2009/0298006	A1 *	12/2009	Schwartz
	10,555,792	B2	2/2020	Kopelman et al.				A61C 7/08
	10,588,776	B2	3/2020	Cam et al.				433/34
	10,613,515	B2	4/2020	Cramer et al.	2010/0055635	A1	3/2010	Kakavand
	10,639,134	B2	5/2020	Shanjani et al.	2010/0129763	A1	5/2010	Kuo
	10,743,964	B2	8/2020	Wu et al.	2011/0020761	A1 *	1/2011	Kalili
	10,758,323	B2	9/2020	Kopelman				A61C 7/08
	10,781,274	B2	9/2020	Liska et al.				433/214
	10,813,720	B2	10/2020	Grove et al.	2011/0039223	A1 *	2/2011	Li
	10,874,483	B2	12/2020	Boronkay				B29C 45/0001
	10,881,487	B2	1/2021	Cam et al.				264/16
	10,912,629	B2	2/2021	Tanugula et al.	2011/0269092	A1	11/2011	Kuo et al.
	10,959,810	B2	3/2021	Li et al.	2012/0315484	A1 *	12/2012	Riedl
	10,973,613	B2 *	4/2021	Li				B29C 48/307
	10,993,783	B2	5/2021	Wu et al.				156/306.6
	11,026,768	B2	6/2021	Moss et al.	2014/0067334	A1	3/2014	Kuo
	11,026,831	B2	6/2021	Kuo	2015/0265376	A1	9/2015	Kopelman
	11,045,282	B2	6/2021	Kopelman et al.	2015/0366638	A1	12/2015	Kopelman et al.
	11,045,283	B2	6/2021	Riley et al.	2015/0374464	A1 *	12/2015	Stewart
	11,103,330	B2	8/2021	Webber et al.				C09K 11/06
	11,109,946	B2 *	9/2021	Venkatasanthanam				264/16
				B32B 38/145				
	11,123,156	B2	9/2021	Cam et al.	2016/0193014	A1	7/2016	Morton et al.
	11,154,382	B2	10/2021	Kopelman et al.	2017/0007359	A1	1/2017	Kopelman et al.
	11,154,384	B2 *	10/2021	Li	2017/0007360	A1	1/2017	Kopelman et al.
	11,166,788	B2	11/2021	Webber	2017/0007361	A1	1/2017	Boronkay et al.
	11,174,338	B2	11/2021	Liska et al.	2017/0007366	A1	1/2017	Kopelman et al.
	11,213,369	B2 *	1/2022	Li	2017/0007386	A1	1/2017	Mason et al.
	11,219,506	B2	1/2022	Shanjani et al.	2017/0135792	A1	5/2017	Webber
	11,259,896	B2	3/2022	Matov et al.	2017/0135793	A1	5/2017	Webber et al.
	11,273,011	B2	3/2022	Shanjani et al.	2017/0165032	A1	6/2017	Webber et al.
	11,278,375	B2	3/2022	Wang et al.	2018/0360567	A1	12/2018	Xue et al.
	11,318,667	B2	5/2022	Mojdeh et al.	2019/0000592	A1	1/2019	Cam et al.
	11,331,166	B2	5/2022	Morton et al.	2019/0000593	A1	1/2019	Cam et al.
	11,344,385	B2	5/2022	Morton et al.	2019/0021817	A1	1/2019	Sato et al.
	11,376,101	B2	7/2022	Sato et al.	2019/0046297	A1	2/2019	Kopelman et al.
	2002/0146549	A1 *	10/2002	Kranenburg-Van Dijk	2019/0099129	A1	4/2019	Kopelman et al.
				B32B 27/06	2019/0125494	A1	5/2019	Li et al.
				428/480	2019/0125497	A1	5/2019	Derakhshan et al.
	2004/0146670	A1 *	7/2004	Chin	2019/0152152	A1	5/2019	O'Leary et al.
				B29C 48/13	2019/0159870	A1 *	5/2019	Li
				428/35.2	2019/0175304	A1	6/2019	Morton et al.
	2004/0166462	A1	8/2004	Phan et al.	2019/0183611	A1 *	6/2019	Li
	2004/0166463	A1	8/2004	Wen et al.	2019/0231484	A1 *	8/2019	Li
	2005/0014105	A1	1/2005	Abolfathi et al.	2019/0262101	A1	8/2019	Shanjani et al.
	2005/0082703	A1 *	4/2005	Wrosz	2019/0298494	A1	10/2019	Webber et al.
				B29C 51/22	2019/0314119	A1	10/2019	Kopelman et al.
				264/16	2019/0343606	A1	11/2019	Wu et al.
	2005/0100853	A1 *	5/2005	Tadros	2020/0000553	A1	1/2020	Makarenkova et al.
				A61C 19/063	2020/0100864	A1	4/2020	Wang et al.
				433/6	2020/0100865	A1	4/2020	Wang et al.
	2005/0186524	A1	8/2005	Abolfathi et al.	2020/0100866	A1	4/2020	Medvinskaya et al.
	2005/0244768	A1	11/2005	Taub et al.	2020/0155276	A1	5/2020	Cam et al.
	2006/0019218	A1	1/2006	Kuo	2020/0188062	A1	6/2020	Kopelman et al.
	2006/0078688	A1 *	4/2006	DeSimone	2020/0214598	A1	7/2020	Li et al.
				A61C 7/08	2020/0214801	A1	7/2020	Wang et al.
				264/494	2020/0390523	A1	12/2020	Sato et al.
	2006/0078841	A1 *	4/2006	DeSimone	2021/0078357	A1 *	3/2021	Venkatasanthanam
				A61C 7/08	2021/0147672	A1	5/2021	Cole et al.
				433/6	2022/0249203	A1 *	8/2022	Li
								B32B 27/286
	2006/0115782	A1	6/2006	Li et al.	FOREIGN PATENT DOCUMENTS			
	2006/0115785	A1	6/2006	Li et al.	CN	108394152	A	8/2018
	2006/0199142	A1	9/2006	Liu et al.	DE	102010036107	A *	3/2012
	2006/0234179	A1	10/2006	Wen et al.	JP	H0696486	A	4/1994
	2007/0087300	A1 *	4/2007	Willison	JP	H07156349	A	6/1995
				A61C 7/12	JP	H11279389	A	10/1999
				433/6	WO	WO 2010/043419	A *	4/2010
	2008/0118882	A1	5/2008	Su				
	2008/0160473	A1	7/2008	Li et al.				

* cited by examiner

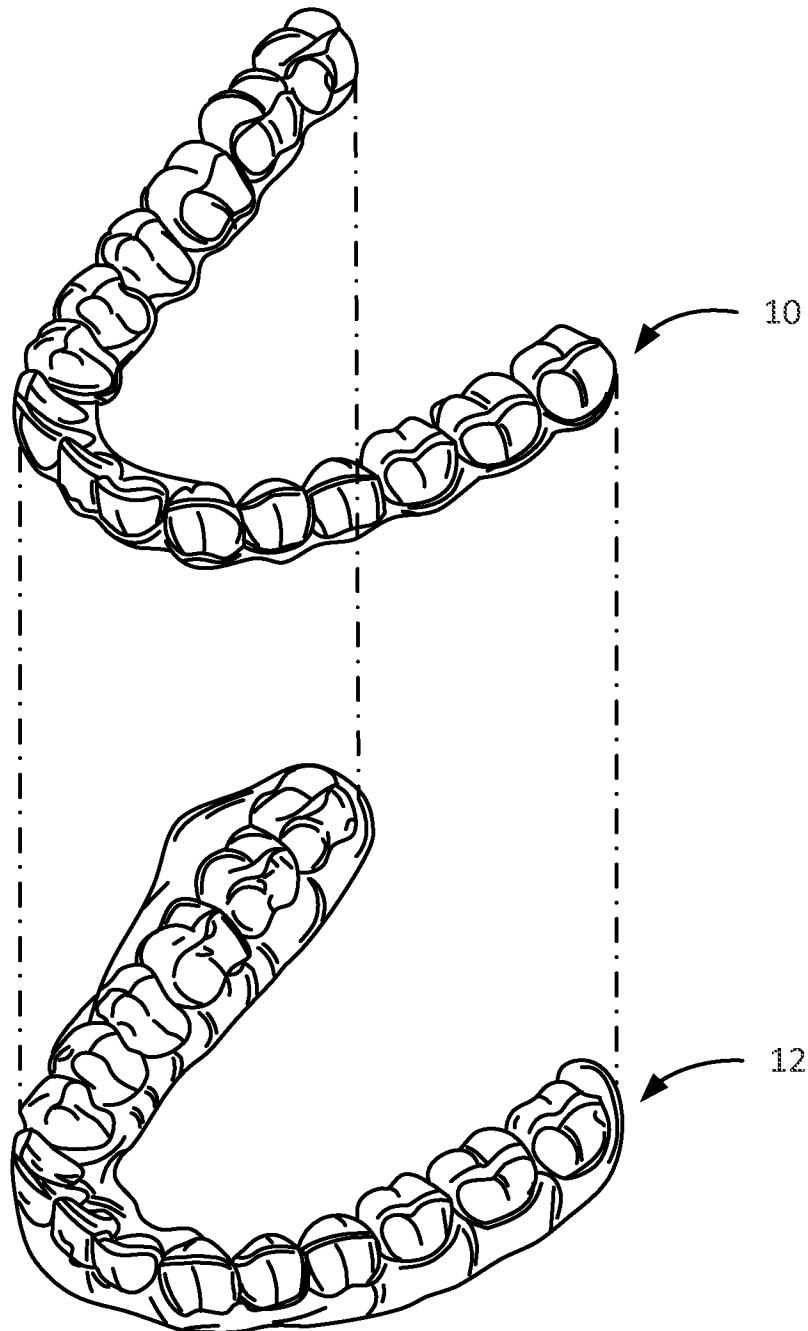


FIG. 1

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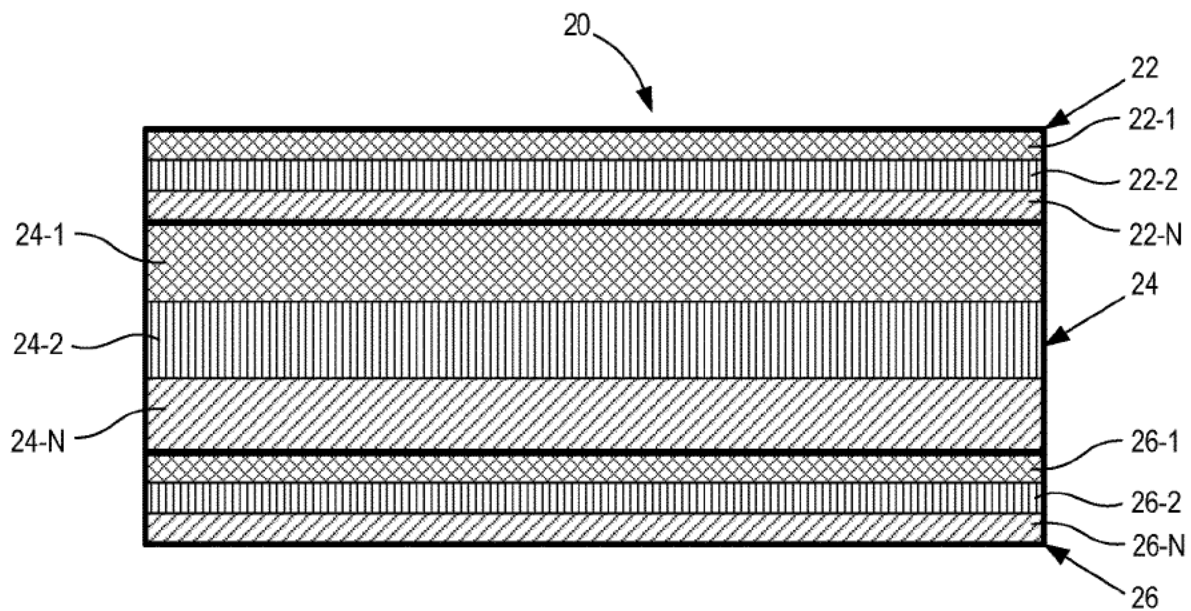


FIG. 2

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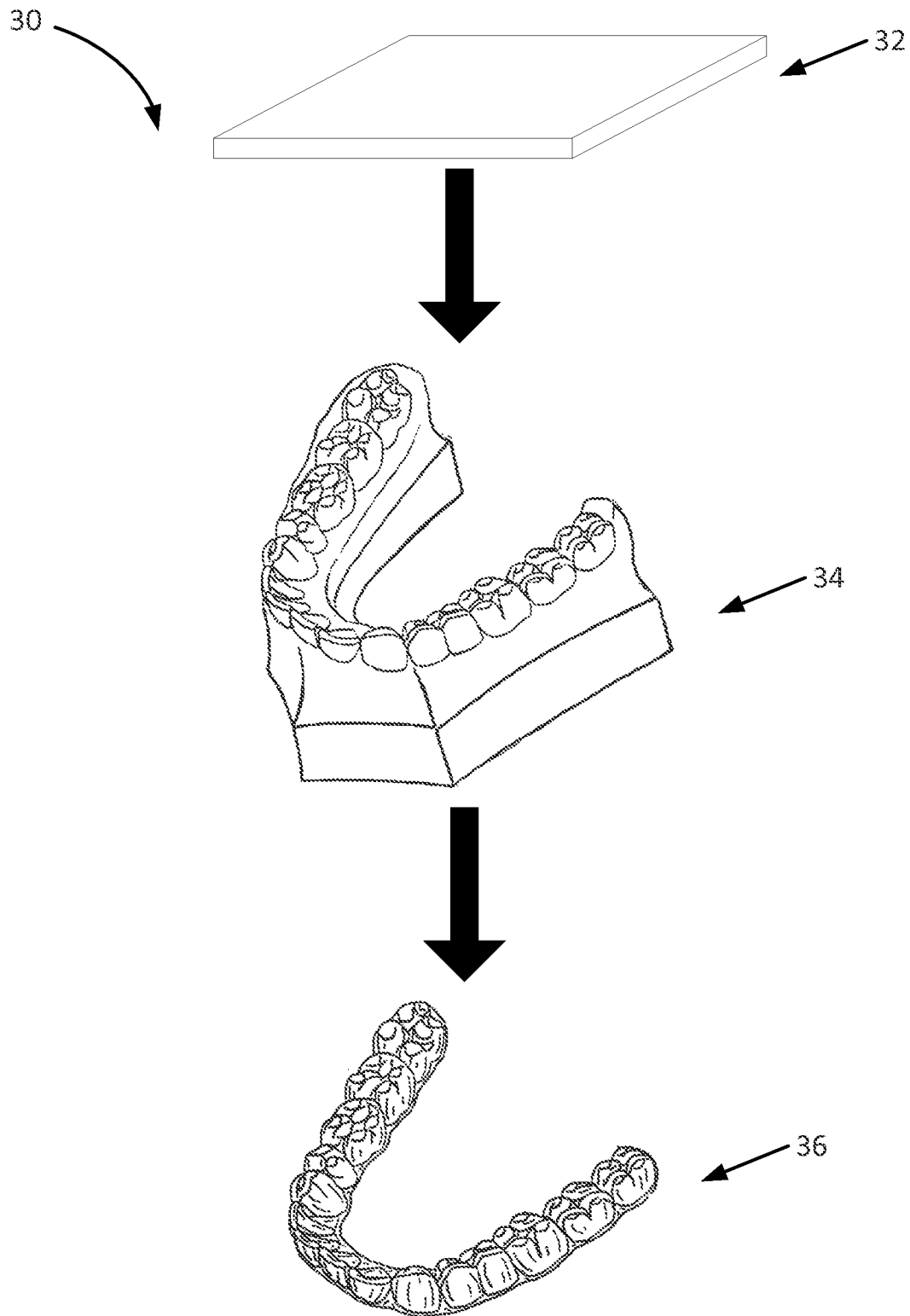


FIG. 3

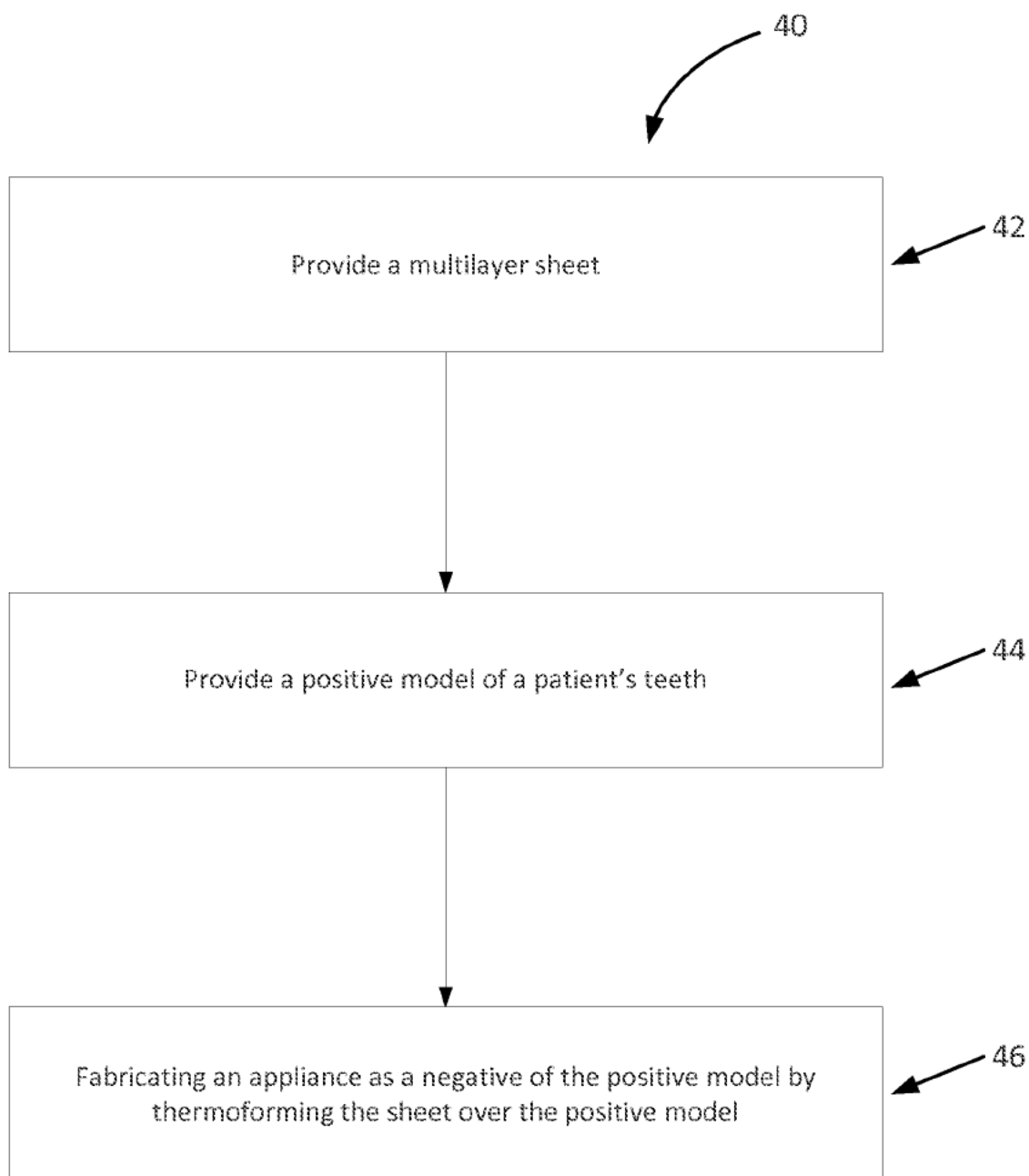


FIG. 4

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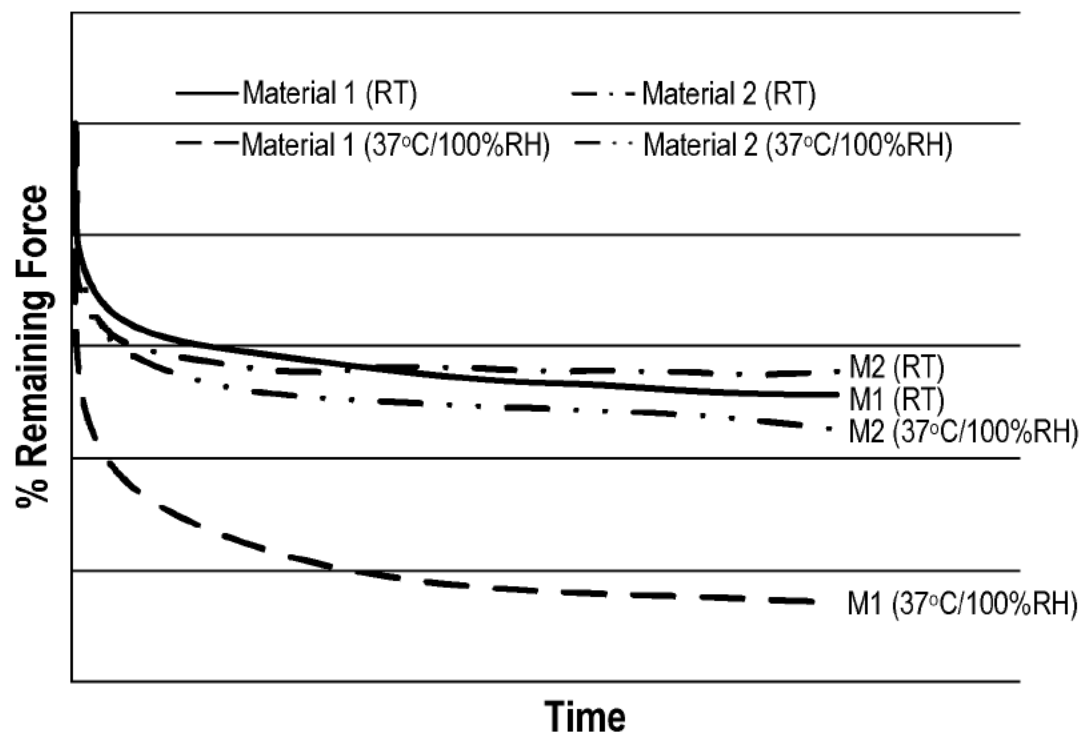


FIG. 5

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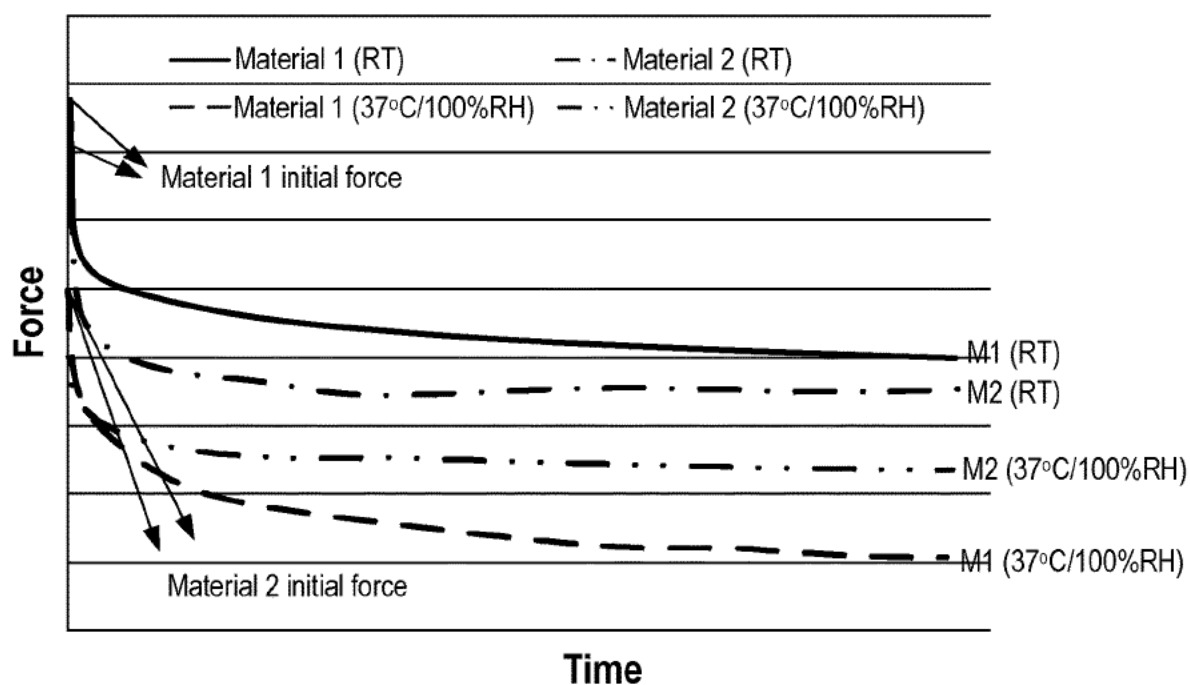


FIG. 6

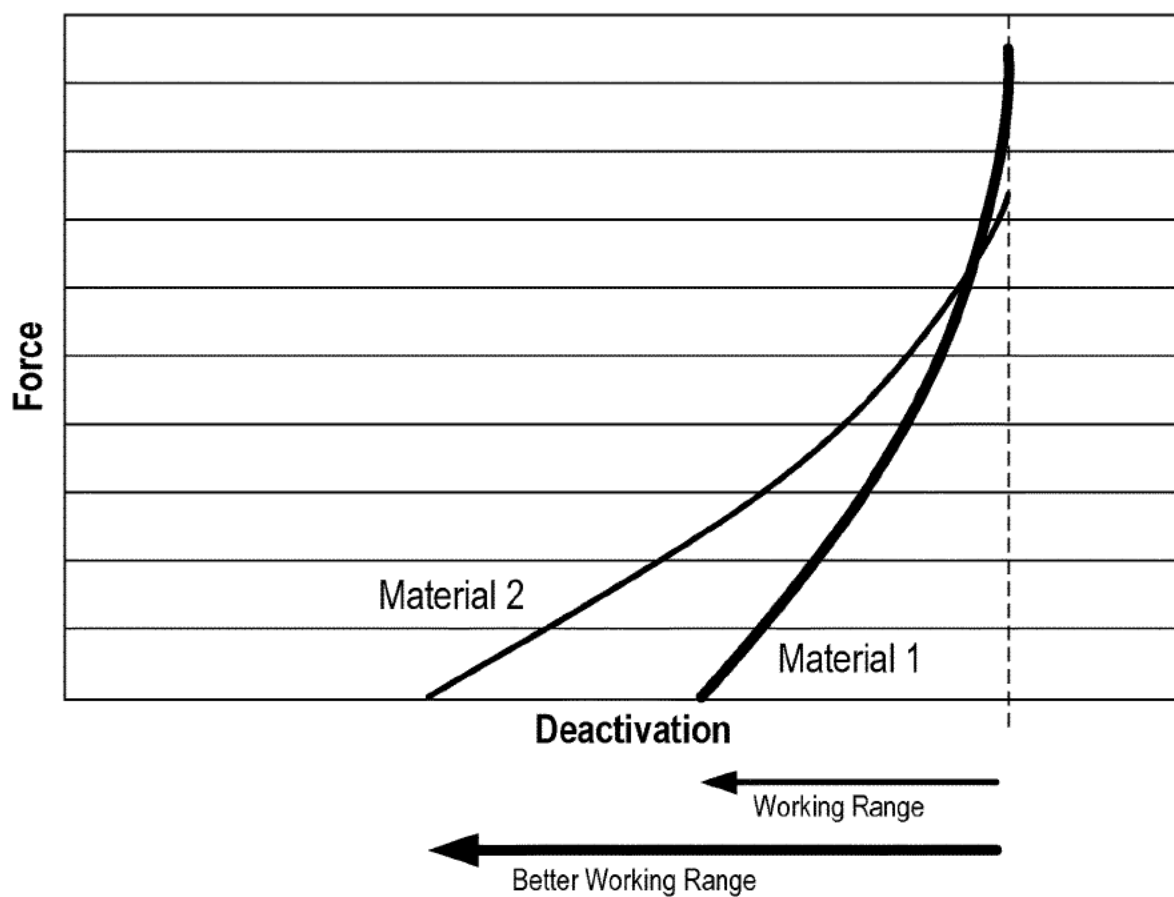


FIG. 7

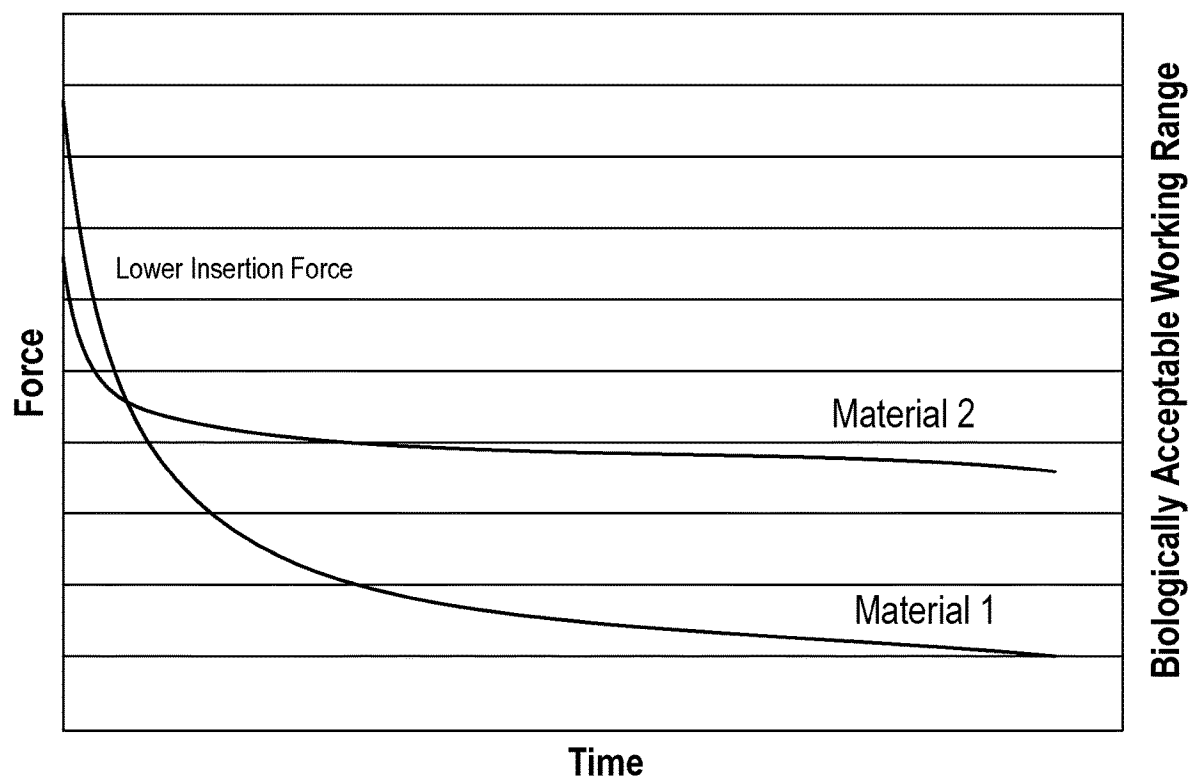


FIG. 8

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MULTILAYER POLYMER SHEETS**CROSS-REFERENCE**

This application is a continuation of U.S. patent application Ser. No. 17/553,590, filed Dec. 16, 2021, which is a continuation of U.S. patent application Ser. No. 16/835,101, filed Mar. 30, 2020, now U.S. Pat. No. 11,213,369, issued Jan. 4, 2022, which is a continuation of U.S. patent application Ser. No. 15/476,655, filed Mar. 31, 2017, now U.S. Pat. No. 10,973,613, issued Apr. 13, 2021, which is a divisional of U.S. patent application Ser. No. 13/470,681, filed May 14, 2012, now U.S. Pat. No. 9,655,691 issued May 23, 2017, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention generally relates to the field of orthodontics, and more particularly to the design of multilayer dental positioning appliances.

An objective of orthodontics is to move a patient's teeth to positions where function and/or aesthetics are optimized. Traditionally, appliances such as braces are applied to a patient's teeth by a treating practitioner and the set of braces exerts continual force on the teeth and gradually urges them toward their intended positions. Over time and with a series of clinical visits and reactive adjustments to the braces by the practitioner, the appliances to move the teeth toward their final destination.

More recently, alternatives to conventional orthodontic treatment with traditional affixed appliances (e.g., braces) have become available. For example, systems including a series of preformed appliances/aligners have become commercially available from Align Technology, Inc., San Jose, Calif., under the trade name Invisalign® System. The Invisalign® System is described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, e.g., the url invisalign.com). The Invisalign® System includes designing and/or fabricating multiple, and sometimes all, of the aligners to be worn by the patient before the aligners are administered to the patient and used to reposition the teeth (e.g., at the outset of treatment). Often, designing and planning a customized treatment for a patient makes use of computer-based 3-dimensional planning/design tools, such as Treat™ software from Align Technology, Inc. The design of the aligners relies on computer modeling of the patient's teeth in a series of planned successive tooth arrangements, and the individual aligners are designed to be worn over the teeth, such that each aligner exerts force on the teeth and elastically repositions the teeth to each of the planned tooth arrangements.

While recently developed orthodontic treatment technologies, such as those described above, represent a considerable advancement in the field of orthodontics, additional advancements remain of interest. For example, in some instances it may be advantageous to develop materials that improve properties of the appliances/aligners used for orthodontic treatment. As such, there is a need for shell aligners that can, for example, produce more continuous force and better bring a patient's teeth into a desired occlusion.

BRIEF SUMMARY OF THE INVENTION

The present invention provides multilayer orthodontic positioning appliances, as well as related methods and

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systems. The disclosed multilayer appliances include a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth. The multilayer appliances can include a hard polymer layer disposed between two soft polymer layers. The multilayer dental appliances of the present invention, among many aspects, provide, for example, improved material performance, stress relaxation properties and longer working range. In addition, the mechanical properties of the materials and appliances described herein can improve orthodontic treatments by, for example, reducing the need for midcourse corrections during treatment and the number of aligners used for a given treatment.

The disclosed methods include methods for making multilayer dental appliances. The disclosed systems including a plurality of appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth. The appliances can be successively worn by a patient to move teeth from one arrangement to a successive arrangement. At least one of the appliances in the system can include a hard polymer layer disposed between two soft polymer layers.

For a fuller understanding of the nature and advantages of the present invention, reference should be made to the ensuing detailed description and accompanying drawings. Other aspects, objects and advantages of the invention will be apparent from the drawings and detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a jaw and an incremental positioning appliance for the jaw, in accordance with an embodiment of the present invention.

FIG. 2 shows an arrangement of polymer layers in a sheet having a hard polymer layer disposed between two soft polymer layers, in accordance with an embodiment of the present invention.

FIG. 3 depicts a method of making a multilayer dental appliance, in accordance with an embodiment of the present invention.

FIG. 4 is a simplified block diagram illustrating a method for fabricating a dental appliance, in accordance with an embodiment of the present invention.

FIG. 5 provides a stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention.

FIG. 6 provides another stress relaxation comparison for dental appliances, in accordance with an embodiment of the present invention.

FIG. 7 shows a long-term unloading comparison for dental appliances, in accordance with an embodiment of the present invention.

FIG. 8 provides a long-term movement comparison for dental appliances, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various embodiments of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodi-

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ments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

Multilayer orthodontic positioning appliances are provided, as well as related methods and systems. During orthodontic treatment, it may be necessary to apply forces to a tooth to generate movement of the tooth to, for example, bring the patient's teeth into a better occlusion in a mesial or distal direction. The presently disclosed appliances, methods, and systems provide means by which such forces can be applied during orthodontic treatment where appliances having teeth receiving cavities are used, such as preformed appliances/aligners available from Align Technology, Inc., San Jose, Calif., under the trade name Invisalign® System. As provided by the present invention, the aligners that include multilayer sheets can, for example, provide increased durability of the aligners so that they can better withstand wear due to aligner reinsertion and removal and other mechanical stresses put on the aligner during treatment. In addition, the aligners have improved elastic properties that allow for less degradation in the shape of the teeth receiving cavities during a stage of treatment. For example, during a multistage orthodontic treatment, the force exerted by an aligner to perform defined tooth movement can degrade and may cause the treatment to include more aligners to reach a final ideal arrangement and/or result in a mid-course correction that could be prevented by using aligners with improved physical properties, such as those provided herein.

In one embodiment, the present invention provides a dental appliance for positioning a patient's teeth. The dental appliance can include a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, the appliance comprising a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

In another embodiment, the present invention provides an orthodontic system for positioning a patient's teeth. The orthodontic system can include a plurality of incremental position adjustment appliances having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, wherein the appliances are successively worn by a patient to move teeth from one arrangement to a successive arrangement, and wherein at least one of the appliances comprises a hard polymer layer disposed between a first soft polymer layer and a second soft polymer layer.

In yet another embodiment, the present invention provides a method of making a dental appliance for positioning a patient's teeth. The method can include providing a sheet comprising a hard polymer layer of polymeric material disposed between a first soft polymer layer and a second soft polymer layer, providing a positive model of the patient's teeth in a target position; and fabricating an appliance as a negative of the positive model comprising thermoforming the sheet over the positive model.

Referring now to the drawings, in which like reference numerals represent like parts throughout the several views, FIG. 1 provides an appropriate starting point in a detailed discussion of various embodiments of the present invention with respect to tooth repositioning appliances designed to apply repositioning forces to teeth. A tooth repositioning appliance 10 can be worn by a patient in order to achieve an incremental repositioning of individual teeth in the jaw 12.

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The appliance can include a shell (e.g., a polymeric shell) having teeth-receiving cavities that receive and resiliently reposition the teeth. In many embodiments, a polymeric appliance can be formed from a sheet of suitable layers of polymeric material. An appliance can fit over all teeth present in an upper or lower jaw, or less than all of the teeth. In some cases, only certain teeth received by an appliance will be repositioned by the appliance while other teeth can provide a base or anchor region for holding the appliance in place as it applies force against the tooth or teeth targeted for repositioning. In some cases, many or most, and even all, of the teeth will be repositioned at some point during treatment. Teeth that are moved can also serve as a base or anchor for holding the appliance as it is worn by the patient. Typically, no wires or other means will be provided for holding an appliance in place over the teeth. In some cases, however, it may be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance so that the appliance can apply a selected force on the tooth. Exemplary appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. Pat. Nos. 6,450,807, and 5,975,893, as well as on the company's website, which is accessible on the World Wide Web (see, e.g., the url invisalign.com”).

An appliance can be designed and/or provided as part of a set of a plurality of appliances. In such an embodiment, each appliance may be configured so a tooth-receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth can be progressively repositioned from an initial tooth arrangement to a target tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. A target tooth arrangement can be a planned final tooth arrangement selected for the patient's teeth at the end of all planned orthodontic treatment. Alternatively, a target arrangement can be one of many intermediate arrangements for the patient's teeth during the course of orthodontic treatment, which may include where surgery is recommended, where inter-proximal reduction (IPR) is appropriate, where a progress check is scheduled, where anchor placement is best, where palatal expansion is desirable, etc. As such, it is understood that a target tooth arrangement can be any planned resulting arrangement for the patient's teeth that follows one or more incremental repositioning stages. Likewise, an initial tooth arrangement can be any initial arrangement for the patient's teeth that is followed by one or more incremental repositioning stages. The adjustment appliances can be generated all at the same stage or in sets or batches, e.g., at the beginning of a stage of the treatment, and the patient wears each appliance until the pressure of each appliance on the teeth can no longer be felt or has resulted in the maximum amount of expressed tooth movement for that given stage. A plurality of different appliances (e.g., set) can be designed and even fabricated prior to the patient wearing any appliance of the plurality. After wearing an appliance for an appropriate period of time, the patient replaces the current appliance with the next appliance in the series until no more appliances remain. The appliances are generally not affixed to the teeth and the patient may place and replace the appliances at any time during the procedure (e.g., patient-removable appliances). The final appliance or several appliances in the series may have a geometry or geometries selected to overcorrect the tooth arrangement, i.e., have a geometry which would (if fully achieved) move individual teeth beyond the tooth

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arrangement which has been selected as the "final." Such over-correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e., to permit movement of individual teeth back toward their pre-corrected positions. Over-correction may also be beneficial to speed the rate of correction, i.e., by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, the use of an appliance can be terminated before the teeth reach the positions defined by the appliance.

In general, structures, methods and systems of the present invention utilize a multilayer sheet for use in orthodontic appliances. The multilayer sheet can include three layers, in which a hard polymer layer is disposed between two soft polymer layers. The multilayer sheets used in the present invention can be used in making dental aligners having improved durability for use, e.g., to the elastic properties of the multilayer sheet when formed into an aligner. In addition, the bonding strength between the layers further improves the durability of the aligners, for example, by withstanding teeth grinding by a patient.

FIG. 2 shows a multilayer structure according to the present invention. As shown, a multilayer sheet 20 can include a three layer structure: a hard polymer layer 24 and two soft polymer layers 22, 26. The hard polymer layer can be disposed between a first soft polymer layer and a second soft polymer layer. In some embodiments, the hard polymer layer can be thicker than either of the soft polymer layers. The soft polymer layers can have the same or different thicknesses. For example, the hard polymer layer can have a thickness in a range from about 400 μm to about 1100 μm , about 450 μm to about 1000 μm , about 500 μm to about 900 μm , or about 550 μm to about 750 μm . The soft polymer layers can have a thickness in a range from about 25 μm to about 100 μm , about 30 μm to about 90 μm , or about 35 μm to about 80 μm . Multilayer sheets used for making appliances having a hard polymer layer disposed between two soft polymer layers can range from a thickness of about 500 μm to about 1200 μm , about 550 μm to about 1100 μm , or about 600 μm to about 1000 μm . In some embodiments, the thicknesses of the various layers can be tailored for a particular stage of treatment for the patient.

Suitable polymeric materials for the hard polymer layer can include a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate or a combination thereof (e.g., a blend of at least two of the listed hard polymeric materials). In some embodiments, the hard polymer layer of the appliances can include polymeric materials, such as a polycarbonate, a co-polyester, a polyester, and a thermoplastic polyurethane. In some embodiments, the hard layer can be composed of multiple hard layers, e.g., two or three hard polymer layers 24-1, 24-2, 24-N co-extruded to form one hard layer.

The hard polymer layer of the appliances of the present invention can have a variety of physical properties that can, e.g., improve treatment options for a practitioner. For example, physical properties such as tensile strength, elongation at yield, elongation at break, tensile modulus, flexural modulus, stress relaxation over time, and light transmission can each be specifically tailored for a particular application. In some embodiments, the hard polymer layer of the appli-

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ances can have a physical property of at least one of a tensile strength at yield of between about 4000 pounds per square inch (psi) and 6500 psi, an elongation at yield of greater than about 4%, an elongation at break of greater than about 70%, a tensile modulus of greater than about 150,000 psi, a flexural modulus greater than about 150,000 psi, a stress relaxation at 24 hours testing in a wet environment (e.g., between about 90%-100% relative humidity) is greater than 10%, and a light transmission between 400 nm and 800 nm of greater than about 75%.

Suitable polymeric materials for the soft polymer layers of the appliance can include a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend elastomer, a thermoplastic co-polyester elastomer, a thermoplastic polyamide elastomer, or a combination thereof (e.g., a blend of at least two of the listed soft polymeric materials). The soft polymer layers can be the same material or a different material. In certain embodiments, the first soft polymer layer and the second soft polymer layer are the same polymeric material.

The soft polymer layers of the appliances can have a variety of physical properties. For example, physical properties such as hardness, ultimate tensile strength, elongation at break, tensile modulus, compression set, flexural modulus, and light transmission can each be specifically tailored for a particular application. In some embodiments, the soft polymer layers of the appliances can independently have a physical property of at least one of a hardness of about 60A to about 85D, an ultimate tensile strength of greater than about 5000 psi, an elongation at break of greater than about 200%, a compression set at about 70° C. of greater than 40% after 24 hours, a flexural modulus of greater than about 35,000 psi, and a light transmission between 400 nm and 800 nm of greater than about 75%.

As described herein, the layers of the appliances can include a hard polymer layer disposed between two soft polymer layers. In one embodiment, the multilayer appliances can include a hard polymer layer of one type of material (e.g., a co-polyester), and two soft polymer layers of other types of material that can be the same or different (e.g., two soft polymer layers of thermoplastic polyurethane elastomer). In some embodiments, the multilayer appliances can also include a hard polymer layer of at least two layers of polymer material. For example, the hard polymer layer can include several polymer layers laminated together to form the hard polymer layer. The laminated hard polymer layer can include at least two layers of any combination of the following polymer materials: a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, and a polytrimethylene terephthalate. Similarly, in some embodiments, the multilayer appliances can include a soft polymer layer of at least two layers of polymer material. For example, the soft polymer layers 22, 26 can include a layer of several polymer layers 22-1, 22-2, 22-N and 26-1, 26-2, 26-N, respectively, laminated together. The laminated soft polymer layers can include at least two layers of any combination of the following polymer materials: a styrenic block copolymer (SBC), a silicone rubber, an elastomeric alloy, a thermoplastic elastomer (TPE), a thermoplastic vulcanizate (TPV) elastomer, a polyurethane elastomer, a block copolymer elastomer, a polyolefin blend

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elastomer, a thermoplastic co-polyester elastomer, and a thermoplastic polyamide elastomer.

The tooth positioning appliances can be fabricated using a variety of methods. For example, methods for making the appliances can include thermoforming a multilayer sheet into an aligner by heating the sheet and then molding the sheet to a particular configuration. Exemplary methods for fabricating the appliances, including those utilized in the Invisalign® System, are described in numerous patents and patent applications assigned to Align Technology, Inc. including, for example, in U.S. application Ser. No. 13/186,374 as well as on the company's website, which is accessible on the World Wide Web (see, e.g., the url invisalign.com”).

FIG. 3 depicts an example embodiment of a process 30 for forming a multilayer tooth positioning appliance, in accordance with an embodiment of the present invention. As shown, a multilayer sheet 32 can be formed into a tooth positioning appliance 36. The multilayer sheet 32, as depicted, can include three layers: a hard polymer layer disposed between two soft polymer layers. In this example process, the tooth positioning appliance 36 can be produced with the use of a physical tooth model, or mold, 34. The tooth positioning appliance 36 can be produced by heating the thermoformable multilayer sheet 32 and then vacuum or pressure forming the sheet over the teeth in the physical tooth model 34. The tooth positioning appliance 36 is a direct representation of the physical tooth model. Excess material from the sheet can be trimmed to form a final tooth positioning appliance that can be used for orthodontic treatment of a patient.

One or a series of physical tooth models, such as the model described above, may be used in the generation of elastic repositioning appliances for orthodontic treatment. Similar to the process above, each of the appliances can be generated by thermoforming a multilayer polymeric material over a mold of a desired tooth arrangement to form a dental appliance. The tooth positioning appliance of the desired tooth arrangement generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled forces in specific locations to gradually move the teeth into the desired configuration. Repetition of this process with successive appliances comprising new configurations eventually moves the teeth through a series of intermediate configurations to a final desired configuration.

The present invention includes a variety of methods for fabricating dental appliances. FIG. 4 shows a simple schematic for a method 40 of fabricating a removable orthodontic tooth positioning appliance having teeth receiving cavities shaped to directly receive at least some of the patient's teeth and apply a resilient positioning force to the patient's teeth, in accordance with an embodiment of the present invention. The method can include providing a multilayer sheet having a hard polymer layer disposed between two soft polymer layers (Step 42). The method can further include providing a positive physical model of a patient's teeth (Step 44). The tooth positioning appliance can be fabricated by thermoforming the multilayer sheet over the positive physical model (Step 46), in which the tooth positioning appliance is a negative of the positive model. As described above, the methods of fabrication can further include trimming or cutting portions of the sheet to render a final, usable appliance for orthodontic treatment.

Multilayer sheets of the present invention were analyzed and determined to provide a variety of improved properties for aligners used in orthodontic treatment. As further described herein, the multilayer sheets formed into aligners

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can, for example, provide increased durability of the aligners so that they can better withstand wear due to teeth grinding and other mechanical stresses put on the aligner during treatment. In addition, the aligners have improved elastic properties that allow for less degradation in the shape of the teeth receiving cavities during a stage of treatment. For example, during a multistage orthodontic treatment, the capability of an aligner to force tooth movement can degrade and may cause the treatment to include more aligners to reach a final ideal arrangement and/or result in a mid-course correction that could be prevented by using aligners with improved physical properties, such as those provided herein.

FIGS. 5-8 provide example test results that compare various physical properties of the multilayer sheet appliances of the present invention with other already existing aligner materials (Material 1). Samples of varied thicknesses were tested. For example, multilayer sheets were tested having a hard polymer layer with thicknesses ranging from about 580 μm to about 715 μm thick. In some examples, the hard layer was a co-polyester hard polymer layer. The soft layers tested ranged between about 50 μm to about 100 μm . In some examples, the hard polymer layer was disposed between thermoplastic polyurethane elastomer soft polymer layers. As shown in FIGS. 5 and 6, one example of the multilayer sheet material (Material 2) showed improved stress relaxation properties as compared to another already existing material (Material 1) at room temperature and at a 37° C./90-100% relative humidity condition. In addition, FIG. 7 shows improved long-term unloading characteristics of the multilayer sheet Material 2 versus the already existing Material 1 in a 37° C./90-100% relative humidity condition. The multilayer sheet showed less deflection under force loads. FIG. 8 also shows improved long-term movement data for the multilayer sheet Material 2 versus Material 1 in a 37° C./90-100% relative humidity condition.

The use of the terms “a” and “an” and “the” and similar referents in the context of describing embodiments (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., “such as”) provided herein, is intended merely to better illuminate embodiments and does not pose a limitation on the scope unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of at least one embodiment.

Variations of the embodiments described herein may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for embodiments to be constructed otherwise than as specifically described herein. Accordingly, suitable embodiments include all modifications and equiva-

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lents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is contemplated as being incorporated into some suitable embodiment unless otherwise indicated herein or otherwise clearly contradicted by context. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the pending claims along with their full scope or equivalents.

What is claimed is:

1. A method of making a multilayer dental aligner for repositioning a patient's teeth from a first arrangement toward a second arrangement, the method comprising:

providing a multilayer sheet comprising three polymer layers, the three polymer layers comprising:

a first layer consisting of a co-polyester, the co-polyester having a flexural modulus greater than 150,000 psi, an elongation at yield of greater than 4%, a tensile modulus greater than 150,000 psi, a tensile strength at yield of 4000-6500 psi, and an elongation at break of greater than 70%; and

a second layer consisting of a thermoplastic polyurethane elastomer, the thermoplastic polyurethane elastomer having an ultimate tensile strength of greater than 5000 psi, an elongation at break of greater than 200%, and a hardness of 60A to 85D; and

a third layer;

wherein the co-polyester has an elastic modulus greater than the thermoplastic polyurethane elastomer;

providing a mold;

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thermoforming the multilayer sheet over the mold to form a plurality of tooth-receiving cavities configured to receive and reposition the patient's teeth from the first arrangement toward the second arrangement; and trimming excess material from the thermoformed multilayer sheet to form the multilayer dental aligner.

2. The method of claim 1, wherein the co-polyester has a light transmission between 400 nm and 800 nm of greater than about 75%.

3. The method of claim 1, wherein the third layer comprises a same or different co-polyester.

4. The method of claim 1, wherein the first layer is disposed adjacent to the third layer.

5. The method of claim 1, wherein the first layer is coextruded with or laminated to the third layer.

6. The method of claim 1, wherein the multilayer sheet further comprises a fourth layer comprising a same or different thermoplastic polyurethane elastomer.

7. The method of claim 6, wherein the first layer and the third layer are disposed between the second layer and the fourth layer.

8. The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a compression set at about 70° C. of greater than 40% after 24 hours.

9. The method of claim 1, wherein the thermoplastic polyurethane elastomer comprises a light transmission between 400 nm and 800 nm of greater than about 75%.

10. The method of claim 1, wherein the co-polyester has a stress relaxation at 24 hours in a wet environment of between 90-100% humidity of greater than 10%.

11. The method of claim 1, wherein the first layer is thicker than the second layer.

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